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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/108,189	07/01/1998	HOWARD TANNER	23660-00611	9021

25243 7590 12/01/2001

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EXAMINER

THISSELL, JEREMY

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/01/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/108,189

Applicant(s)

Tanner et al.

Examiner

Jeremy Thissell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 27, 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 82, 85-87, and 96-114 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 104-114 is/are allowed.
- 6) ☒ Claim(s) 82, 85-87, 96-100, 102, and 103 is/are rejected.
- 7) ☒ Claim(s) 101 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 82, 85-87, 96-98, 100, and 102 are rejected under 35 U.S.C. 102(e) as being anticipated by Hermann et al (US Pat No. 5,599,305).

Hermann teaches a introducer sheath having a positioning balloon 78 (see figure 6), and a sealing material 38 (see figure 8) in the sheath for surrounding and sealing the passage around surgical instruments introduced through the sheath. Hermann distinctly shows in figure 3 and teaches in col. 10, lines 4-9) that the sealing material does not readily form a passage when it is inserted in the housing (normal arrangement during use). Figure 4 is merely a drawing of the material if it were not inside the device. Hermann also teaches inflation lumens 80/82 (running along the instrument passageway) for the balloon(s). Lastly, Hermann teaches that the inner liner is formed of a polymer (col. 6, lines 21-24).

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 99 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hermann et al (US 5,599,305).

Hermann teaches all the claimed subject matter but does not specifically teach that the outer surface of the device is made of silicon. However, Hermann does teach that the inner surface is coated with silicone in order to provide lubricity (col. 3, line 67). Since silicone is a well known lubricious material used to manufacture many different components of catheters, and since Hermann uses silicone to provide lubricity in the inner lumen, one would have found it obvious to choose silicone for the outer surface in order to provide a lubricious surface to facilitate insertion of the device.

5. Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hermann '305 in view of Fettel et al (US 3,978,863).

Hermann teaches substantially all the claimed subject matter but does not teach that saline is used to inflate the balloon. However, the use of saline is universal in the art of catheters, and this

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point is supported by Fettel, who teaches that in “the most commonly used prior art catheter...a fluid, such as saline....is used to expand the balloon” (col. 1, lines 46 and 63-65). Saline is typically used instead of a gas when the device is used intravascularly in case the balloon breaks, because if the balloon breaks and the gas escapes into the vasculature, the highly compressible gas will allow the patient’s blood pressure to drop too far thus rendering the circulation ineffective causing the death of the patient. Saline is also used because it is most similar to the fluid throughout the body and consequently creates little if any imbalance when introduced to the body. In view of this extreme commonality and the teachings of Fettel, it would have been obvious to use saline as taught by Fettel to inflate the balloon of Hermann particularly during intravascular procedures in order to prevent the entry of a gas into the vascular system.

Allowable Subject Matter

6. Claim 101 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
7. Claims 104-114 are allowable over the prior art of record.
8. The prior art does not teach that the sealing material is a self-sealing gel-like material, but rather a foam

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Response to Arguments

9. Applicant's arguments filed 27 August 2001 have been fully considered but they are not persuasive.

Again, the examiner takes the position that Hermann DOES teach that the sealing material does not readily form a passageway (i.e. lumen).

Applicant pointed out the passage at col. 7, lines 50-54, which states,

"When the foam insert is disposed within the interior housing of the cavity, however, the insert is compressed sufficiently to close the lumen. The resilient nature of the foam will permit the lumen to reopen as the catheter is advanced therethrough."

This passage reinforces the examiner's position that the lumen is "closed" (i.e. no lumen) until a catheter is advanced through the insert, at which point the resilient nature of the insert allows it to stretch open.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the

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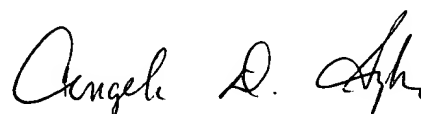
mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy Thissell whose telephone number is (703) 305-5261, or to Supervisory Patent Examiner Angela Sykes at (703)308-5181.

jt

November 7, 2001



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
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